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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,272	08/13/2001	Christoph Kirsch	4038.001	3234
41288	7590	12/27/2005	EXAMINER	
PENDORF & CUTLIFF 5111 MEMORIAL HIGHWAY TAMPA, FL 33634-7356			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,272

Applicant(s)

KIRSCH ET AL.

Examiner

Maria B. Marvich, PhD

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005 and 28 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) 1,4-7,10-21,23-38,40 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 8, 9, 22, 39 and 42-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a response to a restriction requirement filed 9/28/05 and an amendment filed 1/31/05 and 5/6/05. Claim 41 has been cancelled. Claims 1-40 and 42-46 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group II (claims 2, 3, 8, 9, 22, 39 and 42-45 in the reply filed on 9/28/05 is acknowledged. The traversal is on the ground(s) that Group II and Group VIII are related as product and process of using and as the elements in Group II are the essential components, a search of Group II would ultimately yield the end result of Group VIII.

This is not found persuasive because the criteria for separating product and process of using have been set forth in the office action mailed 7/28/03. In the instant case, the chimeric promoter can be used in a materially different process of using that product to generate transgenic plants. The chimeric promoter can be used for recombinant production of proteins *in vitro* or alternatively to function as a hybridization probe. The criteria for establishing that the inventions are distinct and can support separate patents have therefore been met (MPEP 806.05 (h)). Guidance for rejoinder of products and process of using was also provided. Briefly, 'if a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.' For further

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guidance see “Guidance on Treatment of Product and Process Claim in light of *In re Ochiai*, *In re Brouwer* and 35 USC 103(b),” 1184 O.G. 86 (March 26, 1996).

The requirement is still deemed proper and is therefore made FINAL. Therefore, claims 2, 3, 8, 22, 39 and 42-45 are pending in this application. Claims 1, 4-7, 10-21, 22-38, 40 and 46 have been withdrawn as being directed to non-elected subject matter.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. The new grounds of rejection herein were necessitated by amendment and, therefore, this action is final.

Claim Objections

Claim 42 is objected to because of the following informalities: a word is missing between the word “claim” and the word “wherein”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 2, 3, 8, 9, 39 and 42-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections necessitated by applicants’ amendment.**

Claim 2 is vague and indefinite in that the metes and bounds of “two or more cis-acting elements” are unclear. It is unclear if each of the cis-acting elements comprise SEQ ID NO:11 or if the limitations of the claims are met if a promoter with only one copy of SEQ ID NO:11.

Claim 42 recites the limitation "said at least one cis-acting element" in claim 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2, 22 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by van de Locht et al (EMBO J, 1990, vol 9(9) p 2945-2950; see entire document). **This rejection is maintained for reasons of record in the office action mailed 7/28/04 and restated below. This rejection is extended to claim 39, which has been added to the examined claims at examiners discretion. As no new issues are addressed by this introduction and claim 39 is rejected for reasons of record, this rejection is final.**

Van de Locht et al teach a promoter obtainable by insertion of pPR2-10, which comprises at least one cis-acting element sufficient to direct elicitor-specific expression into the promoter of the GUS reporter gene as recited in claim 39. pPR2-10 comprises SEQ ID NO:11 as indicated in figure 5 which demonstrates that pPR2-10 comprises the region from –168 to –43. This region

comprises SEQ ID NO:11 and functions as a cis-element sufficient to direct elicitor specific expression with the CAAT element. Hence the vector comprises at least two-cis acting elements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over van de Loch et al (EMBO J, 1990, vol 9(9) p 2945-2950; see entire document) in view of Pears and Williams (Nucleic Acids Research, 1988, Vol 16(17), pages 8467-84861; see entire document) and Searle et al, MCB, 1985, Vol 5(6), pages 1480-1489; see entire document) further in view of Comai et al (Plant Molecular Biology, 1990, Vol 15(3), pages 373-381; see entire document). **This is a new rejection necessitated by applicants' amendment.**

Applicants claim a chimeric promoter comprising two or more cis-acting elements comprising SEQ ID NO:11. This rejection is directed to an alternative reading of the claim that the promoter comprises at least two copies of SEQ ID NO:11.

The teachings of van de Loch et al are described above and are applied as before except; van de Loch et al do not teach that pPR2-10 comprises two copies of the elicitor element.

Pears and Williams teach that heterologous promoter sequences inserted into promoters can mediate sufficient gene expression (see e.g. abstract). Specifically, Pears and Williams teach

that the promoter elements function “optimally” when multiple copies of the sequences are present (see e.g. page 8480 and figure 7).

Searle et al teach that promoters comprising two heterologous inducible elements isolated from the methallothionein I gene function as strong inducible promoter, whereas a single element did not respond to zinc (see e.g. abstract). Applicants reason that more than two should further increase the inducibility of the promoter.

Comai et al teach that promoters can be duplicated with the effect of enhanced expression (see e.g. abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to duplicate the isolated promoter fragment that is elicitor responsive as taught by van de Locht et al as taught by Pears and Williams and Searle et al and Comai et al because and van de Locht et al teach that a fragment of the PR2 promoter is responsible for strong elicitor mediated gene activation and because Pears and Williams and Searle et al teach that multiple elements are more effective than single elements and Comai et al teach that it is within the ordinary skill of the art to generate chimeric vectors in which larger promoter elements are duplicated. One would have been motivated to do so in order to receive the expected benefit of enhanced regulation of heterologous genes. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 102 on pages 20-23 of the amendment filed 1/31/05. Applicants argue that van de Locht et al identifies a sequence within

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the PR2 promoter that is from position -168 to -52 and this sequence is not the same as SEQ ID NO:11, which corresponds to position -76 to -46. Furthermore, van de Locht et al teach that teaches that position -108 to -52 mediates low level expression. Furthermore, applicants have amended claim 2 to recite that there are at least two cis elements.

Applicants' arguments filed 1/31/05 have been fully considered but they are not persuasive. Claim 2 recites a chimeric promoter, which comprises SEQ ID NO:11 and claim 22 recites a cis-acting element sufficient to direct elicitor-specific expression comprising SEQ ID NO:11. van de Locht et al teach such a promoter and cis-acting element as depicted in figure 5 and teach that this promoter mediates strong elicitor mediated expression as demonstrated in figure 6. The element of van de Locht et al comprise other sequences as the claims recites that the promoter comprises, which is open language the sequences of SEQ ID NO:11. Furthermore, the chimeric promoter allows for more than one cis element as the claim recites inclusion of "two or more cis-acting elements".

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 15, 2005

Maria B Marvich, PhD
Examiner
Art Unit 1633



DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER